



**COVID-19
IMMUNITY
TASK FORCE**

**GROUPE DE TRAVAIL
SUR L'IMMUNITÉ
FACE À LA COVID-19**

**Scientific Strategy, Governance,
and Operational Plan**



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FACE À LA COVID-19**

Final Version

October 19, 2020

Table of Contents

Abbreviations.....	5
1. Mandate.....	6
2. Scientific Strategy.....	6
Figure 1: Overview of the CITF Scientific Strategy Priorities	7
2.1. Field Studies: Population Surveys and Longitudinal Cohorts.....	7
2.1.1. Objectives	8
2.2. Immune Science	8
2.2.1. Objectives	9
2.3. Testing	9
2.3.1. Objectives	10
2.4. Strategic Responsiveness	11
2.5. Working collaboratively and pragmatically	11
3. Governance.....	12
3.1. Principles of the COVID-19 Immunity Taskforce.....	13
3.2. Structure	13
Figure 2: CITF Governance Structure.....	13
3.3. Roles & Responsibilities	14
3.3.1. The Public Health Agency of Canada	14
3.3.2. Leadership Group.....	14
3.3.2.1. Working Parties	15
3.3.3. Executive Committee	16
3.3.4. Secretariat.....	17
Figure 3: Secretariat Structure.....	17
3.3.5. Secretariat – Supplementary Studies.....	19
3.3.6. Host Institution.....	19
3.3.7. Implementing Partners.....	19
4. Investment Notes	20
Figure 4 : Investment Note Process.....	21
5. Conflict of Interest Prevention and Management	21
6. Equity, Diversity and Inclusion and Gender-Based Analysis Plus	22
7. Knowledge Translation and Mobilization Strategy	22

Appendices.....	24
A1: Leadership Group Membership.....	24
A2: Executive Committee Membership	27
A3: Summary of the Secretariat Roles and Responsibilities.....	28
A4: Supplemental Studies.....	31
A5: Host Institution, McGill, Secretariat Facilitation & Management Committee	32

List of Figures

Figure 1: Overview of the CITF Scientific Strategy Priorities	7
Figure 2: Overview of the CITF Governance Structure.....	13
Figure 3: Secretariat Structure	17
Figure 4: Investment Note Process	21

Abbreviations

BSL	Bio-safety Laboratory
CIHR	Canadian Institutes of Health Research
CITF	COVID-19 Immunity Task Force
COI	Conflict of Interest
DGF	Data Governance Framework
EC	Executive Committee of the COVID-19 Immunity Task Force
EDI	Equity, Diversity, and Inclusion
GBA+	Gender-Based Analysis Plus
NML	National Microbiology Laboratory
PHAC	Public Health Agency of Canada
PRNT	Plaque Reduction Neutralization Testing
RFEOI	Requests for Expression of Interest
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
F&MC	Secretariat Facilitation Management Committee (under the leadership of McGill's Vice President Research (VPR))
TOR	Terms of Reference
WP	Working Party

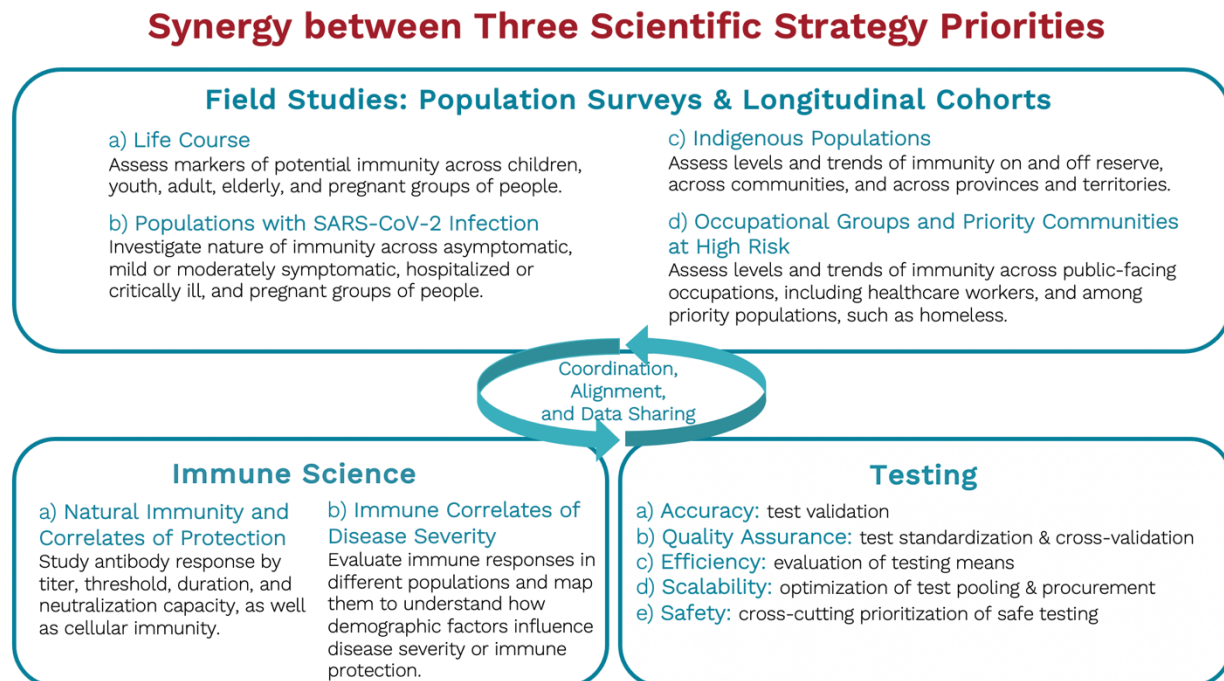
1. Mandate

The **COVID-19 Immunity Task Force (CITF)** was established by the Government of Canada in late April 2020 in order to implement important aspects of the Public Health Agency of Canada (PHAC) **Serosurveillance Program**, addressing the critical need to determine the extent of SARS-CoV-2 infection and understand the nature of immunity following infection. The aims of the CITF are to catalyse, support, and harmonize the design and rapid implementation of population-based studies, where appropriate and feasible. These studies will generate reliable first estimates of SARS-CoV-2 infection and provide insights on the extent of immunity to SARS-CoV2 overall as well as in priority populations across Canada. The CITF supports laboratory studies to establish the advantages and limitations of immunity testing and related technologies and to generate practical insights into optimal ways of using and interpreting these tests. The CITF also supports immune science endeavours to understand humoral and cellular immunity and its implications for susceptibility to and protection from SARS-CoV-2 infection in the Canadian public. These studies are designed to inform federal, provincial, and territorial decision-makers in their efforts to manage the COVID-19 pandemic in the near and medium term.

2. Scientific Strategy

To fulfill its mandate, the CITF developed a **Scientific Strategy** focused on three cross-cutting **priorities**: Field Studies, Immune Science, and Testing. All three priorities operate synergistically, with Field Studies driving serologic data collection from Canadian populations; Immune Science advancing the state of knowledge needed to understand and interpret data on immunity; and Testing fine-tuning methods for procuring accurate data. Together, these three priorities enable the Task Force to generate relevant and reliable information about the patterns of infection and the nature of immunity emerging in response to SARS-CoV-2 across Canada. The Scientific Strategy priorities are shown in Figure 1.

Figure 1: Overview of the CITF Scientific Strategy Priorities



Each priority is led by a **Working Party (WP)** that is responsible for identifying a workplan to guide investments of the CITF over the next two years (See [section 3.3.2.1](#))

2.1. Field Studies: Population Surveys and Longitudinal Cohorts

Early in the pandemic, testing in Canada and around the world focused almost exclusively on the diagnosis of SARS-CoV-2 infection using nucleic acid antigen tests. However, as the pandemic evolved, the evidence base for asymptomatic transmission grew, as did the need to secure information on the true extent of infection across Canada. This involves testing individuals for the presence of antibodies in response to SARS-CoV-2. By evaluating populations that both have and have not been infected, immune testing can illuminate the total number of individuals who have been infected and their socio-demographic distribution. Antibody testing of stored bloods can do that and can also give insight into the timing of the onset of the SARS-CoV-2 outbreak in Canada. Moreover, in developing a better understanding of SARS-CoV-2's patterns of infection, antibody testing can be used to support the evaluation of measures to prevent transmission, as well as to inform future strategies during subsequent waves of infection.

Antibodies and cellular immunity are also critical to understanding individual immunity and socio-demographic trends in immune responses. Individuals who acquire infection develop multiple immune markers and by following them, it is possible to document varying degrees of symptoms over time, gain insight into the nature of the immune response and the degree to which it is protective from re-infection, as well as the

duration of that protection. In this context, the Field Studies WP supports the development and implementation of field studies to determine and report on the levels and trends of exposure, infection, and immunity across the Canadian population. As part of its work, where possible, the Field Studies WP aims to harmonize surveys being conducted across the country.

2.1.1. Objectives

The Field Studies Working Party focuses on the following objectives:

- a) Assess the prevalence of SARS-CoV-2 antibodies across the full life-course of healthy Canadian populations, ranging from children to elderly people, and at appropriate intervals during the CITF's two-year operational period, with attention to geographical representation where possible;
- b) Investigate the evolution of immunity over time among populations that have been infected with SARS-CoV-2 across a spectrum of disease severity, from asymptomatic to symptomatic, including infections requiring and not requiring hospitalization;
- c) Assess the levels and trends of SARS-CoV-2 infection and immunity among Indigenous populations and across the diverse settings in which they live;
- d) Assess the levels and trends of SARS-CoV-2 infection and immunity among vulnerable communities, racialized populations, and across the diverse settings in which they live;
- e) Assess the levels and trends of SARS-CoV-2 infection and immunity among public-facing occupations, including health care workers and others working outside the home, and priority populations at greater risk of acquiring SARS-CoV-2 infection.

2.2. Immune Science

The Immune Science priority of the CITF aims to generate insight into the nature of immunity underlying SARS-CoV-2 infection in the Canadian population. At present, the immune system's response to the newly emergent SARS-CoV-2 is only beginning to be understood. Individuals who become infected generate antibodies to the virus, but the evidence from early studies does not yet definitively show that antibodies are protective from future reinfection. Currently, it is unknown how long a protective immune response lasts, what level of protective response is needed to prevent re-infection, and whether all previously infected persons mount a protective immune response. Thus, a deeper understanding of the immune response to viral infection, and the role of immunity in the coronavirus disease is an essential complement to interpreting population seroprevalence studies.

In this context, the Immune Science WP aims to advance the state of knowledge on immunity on two fronts. First, the Immune Science WP studies natural immunity and correlates of protection. The purpose of these studies is to reveal what immunological

protection exists within different individuals and populations to support our understanding of both the individual and population-level protection emerging from SARS-CoV-2 infection. Protective factors to evaluate include antibody responses by titer, threshold, duration, and neutralization capability, as well as cellular immunity, including T-cell effector responses, T-cell cytotoxicity, NK cell function, and others. By mapping various immunological responses to SARS-CoV-2, the CITF will be in a better position to support the work of the COVID-19 Vaccine Task Force and PHAC as final procurement decisions are made on vaccine candidates and, more importantly, as they are evaluated in Phase 4 surveillance studies.

Second, the Immune Science WP examines immune correlates of disease severity. Comparative studies are used to evaluate responses to SARS-CoV-2 infection in different populations to better elucidate whether the response to infection is asymptomatic, is mildly/moderately symptomatic, or results in severe illness — and whether the initial response to infection influences the degree of subsequent immune protection. Responses are mapped onto the individual’s immunological make-up to understand how demographic factors, such as age, sex, race/ethnicity, and comorbidities, influence coronavirus infection severity or immune protection.

2.2.1. Objectives

Specifically, the Immune Science Working Party focuses on the following objectives:

- a) Advance the understanding of natural immunity and correlates of protection in cross-sectional, observational, and longitudinal studies to both inform the status of individual and population-level protection, as well as to define qualitative immune responses; and,
- b) Examine the immune correlates of disease severity in comparative studies to inform the identification of prognostic markers.

2.3. Testing

The Testing priority of the CITF aims to enable accurate, quality assured, efficient, scalable, and safe immunity testing for SARS-CoV-2 across Canada. Given the novel status of SARS-CoV-2, all immune tests – whether based on blood draws from veins, pin pricks for blood spots, or saliva samples – require validation for accuracy. A test’s accuracy depends on its sensitivity and specificity, and the interpretation of a test is also dependent on the timing of testing in relation to an individual’s infection. Since the start of COVID-19 in Canada, a growing number of serologic antibody tests have been tested for accuracy with variable results. There is a clear need for highly accurate tests, particularly in settings in which there is low prevalence of SARS-CoV-2 infection. High test sensitivity helps identify true positives while high test specificity helps minimize

false positives. Defining the duration of antibody responses will guide testing strategies and help understand the technology's limitations.

Standards for validation and quality assurance of immune assays come under the mandate of the National Microbiology Laboratory (NML). The NML is a CITF Implementing Partner that works in collaboration with a network of laboratories across the country. The CITF has identified a common agenda working with the NML to enhance capacity for assessing accuracy of different types of immunity tests – whether lab-based or for use in remote communities – through the development of reference panels and cross-validation protocols.

To compare and calibrate antibody tests against one another, there is a need for the Testing WP to set reference standards. Using neutralization tests, such as a plaque reduction neutralization or neutralization surrogates, the WP assesses the relationship between antibody concentration and response against the virus. However, some plaque reduction neutralization testing (PRNT) involves potential exposure to live virus and therefore requires bio-safety lab (BSL)-3 infrastructure, which is limited in availability. Modified procedures called pseudo-virus neutralization assays, have therefore been developed that can be performed within more widely available BSL-2 facilities.

Recognizing the limited supply and strong global demand for accurate tests, the CITF is aggregating demand for tests across studies to avoid shortfalls or delays in procurement. Both commercial kits and novel (bespoke) test approaches from Canadian labs are evaluated.

2.3.1. Objectives

The Testing Working Party supports accurate, high quality, efficient, scalable, and safe Canada-wide antibody testing by focusing on the following objectives:

- a) Accelerate validation of serological tests, in close collaboration with the NML;
- b) Standardize and cross-validate selected tests to assess relative performance, in close collaboration with the NML and provincial public health labs;
- c) Evaluate the efficacy and efficiency of different means of testing Canadians, including venepuncture, dried blood spot, and saliva specimens;
- d) Optimize pooling and procurement of tests to enable Canada-wide testing; and,
- e) Evaluate opportunities to test for neutralizing antibodies using a surrogate or pseudo-virus with limited virulence compared to SARS-CoV-2. Determine best practices for assessing cell mediated immunity using high throughput assays.

2.4. Strategic Responsiveness

The Working Parties recognize that changes in our understanding of novel coronavirus infection and immunity are ongoing and rapid. As well, there is a high degree of uncertainty related to what the future holds in terms of further waves of infection. The Working Parties, together with the Secretariat, will keep track of new developments in our understanding SARS-CoV-2 infection and immunity, as well as the evolution of the pandemic, so that the CITF Leadership Group can adjust the Scientific Strategy as appropriate.

2.5. Working collaboratively and pragmatically

Given the urgent and quickly evolving nature of the pandemic, the CITF is committed to working collaboratively and pragmatically. As a first order of business, the CITF undertook a pan-Canadian landscaping survey to identify relevant research activities across Provincial-Territorial health authorities, academic centres, and hospitals (<https://www.covid19immunitytaskforce.ca/survey-for-key-informants-understanding-opportunities-to-assess-covid-19-immunity-in-canada/>). This survey has been supplemented by regular consultations with Provincial-Territorial representatives, through meetings of the Chief Medical Officers of Health, Deputy Ministers or Ministers of Health, and others. Furthermore, the CITF developed a [collaboration with the CIHR](#) to screen research proposals submitted to the COVID-19 Rapid Research Competition. These linkages were complemented by efforts to tap existing blood samples, stored in provincial laboratories, donated by blood donors, or from women as part of antenatal screening, that could be tested rapidly for antibodies. Similarly, the CITF is piggy-backing serology studies on well-established population health research platforms linked to children¹, adults and elders,² and households³. For important study topics where neither the Landscaping Survey, the CIHR collaboration, nor the initial pragmatic partner identification generated a critical mass of researchers, the CITF is implementing [requests for expressions of interest \(RFEOI\)](#) to identify Canadian investigators and partners to assist with these priorities.

Across all studies, the CITF makes efforts to ensure timely availability of accurate and validated antibody tests. Quality and comparability of data across studies are enhanced through the development of a CITF core set of variables for serological surveys (<https://www.covid19immunitytaskforce.ca/covid-19-immunity-task-force-releases-standardized-core-survey-data-elements/>).

¹ [The CHILD Cohort Study](#)

² [Canadian Partnership for Tomorrow's Health \(CanPaTH\)](#), [Canadian Longitudinal Study on Aging \(CLSA\)](#)

³ [Statistics Canada \(StatCAN\)](#)

Recognizing the global mobilization of research on the novel coronavirus and the opportunities at scale that it provides, the CITF is engaging where possible and appropriate with international collaborators. These include, for example, efforts to collaborate with the WHO's SOLIDARITY II studies and with the vaccine development work of the Coalition for Epidemic Preparedness Innovation (CEPI). The CITF has relationships with counterparts in other countries such as the UK and the USA who are stewarding concerted national serologic studies.

3. Governance

3.1. Principles of the COVID-19 Immunity Taskforce

In accordance with the mandate defined by the Government of Canada, CITF will catalyse, support, and, where appropriate and feasible, harmonize the design and rapid implementation of population-based studies. Any individual or organization involved in the planning, implementation and evaluation of matters related to the CITF agrees to uphold the following principles:

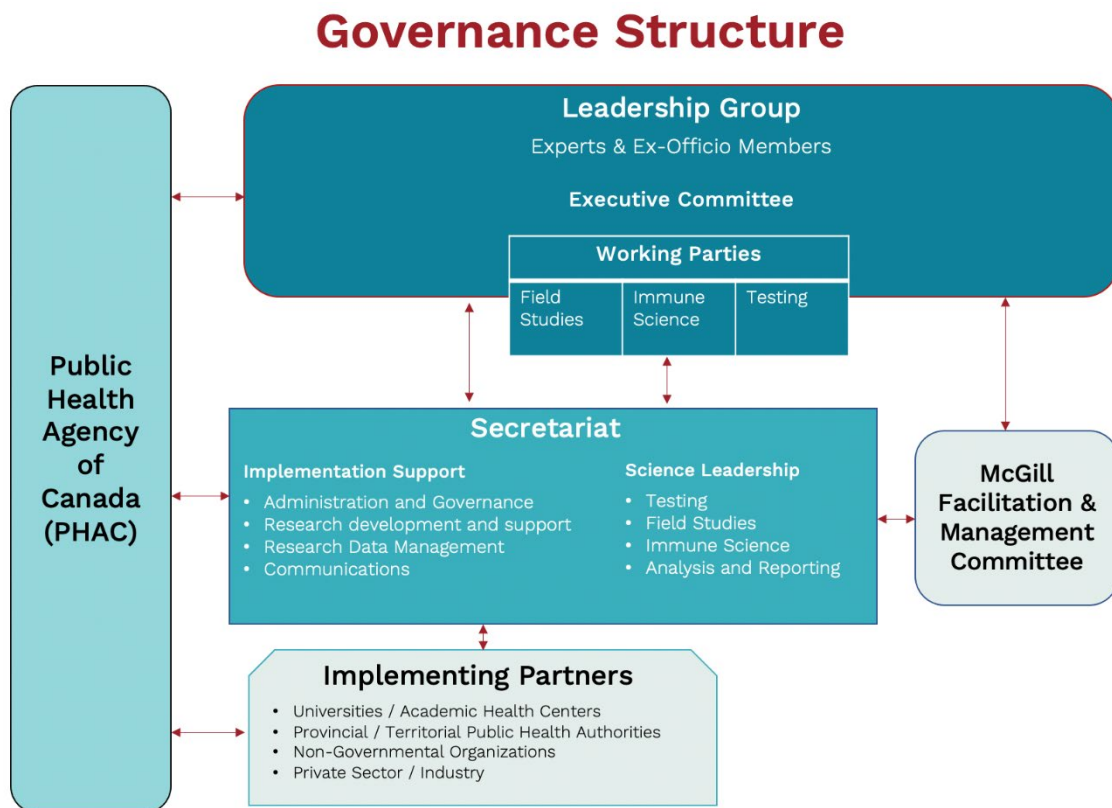
- Partner in all of its work with the Government of Canada, provincial/territorial governments and their agencies, the research community, public health and healthcare professionals/institutions, and a range of community groups;
- Identify priority issues related to serologic testing and its application, paying close attention to diverse needs for information across the country;
- Establish an ethos in which rigorously gathering and rapidly sharing data to inform Canadians and advance the broad public interest over-rides considerations of personal/group advancement;
- Mobilize the best science and study designs recognizing the rapidly evolving state of the science related to serologic testing and understanding of SARS-CoV-2 immunity;
- Establish fair and transparent processes that offer all interested partners across the country an opportunity to participate in the Task Force with an appropriate management of conflicts of interest and a particular attention to equity, diversity and inclusion;
- Work with partners to ensure protection of privacy in data-gathering and safe handling of any and all biological samples;
- Enable the broadest possible impact of the collected research data by ensuring the data is openly available so that researchers can find, access, interpret, and use them to advance knowledge of SARS-CoV-2;
- Collaborate with partners and use existing data- and sample-gathering capacity wherever possible to enhance cost-efficiencies and avoid unnecessary duplication;
- Provide a central coordination for the Task Force that facilitates the rapid development of studies, their effective implementation, and the rapid reporting of results to key audiences, both to decision makers and interested stakeholders, and to the broad Canadian public;

- Promote ethical and sound participatory practices that engage relevant stakeholders from study design through to the dissemination and application of findings;
- Adhere to best practices regarding any authorship of scientific publications eventually arising from this work, while ensuring that all participants understand that this work is in the public interest, requiring rapid dissemination of reliable and relevant results;
- Liaise with relevant entities in other countries, and with international agencies involved in serologic surveys and studies, to understand immunity related to SARS-CoV-2; and,
- Communicate the leadership, membership, activities, and results of the CITF with openness and transparency.

3.2. Structure

The governance structure of the CITF involves five major elements: the Public Health Agency of Canada, a Leadership Group with an Executive Committee, a Secretariat, Implementing Partners, and the Secretariat host institution. The interconnecting relationships between the governance elements are shown in Figure 2.

Figure 2: CITF Governance Structure



3.3. Roles & Responsibilities

3.3.1. The Public Health Agency of Canada

On behalf of the Government of Canada's emergency response to the pandemic, the **Public Health Agency of Canada (PHAC)** oversees the CITF and has the following responsibilities:

- Appoint members of the Leadership Group;
- Finance the activities and operations of the CITF through funding agreements with the host institution and Implementing Partners to undertake studies in the priority areas, as well as with the host institution for operations of the Secretariat via the COVID-19 Serosurveillance and Research program;
- Set standards for immunoassay testing through the National Microbiology Laboratory (NML);
- Provide regulatory approval through Health Canada for assays/tests developed by commercial producers; and,
- Ensure timely procurement and distribution of serologic tests that meet standards/regulatory approval on behalf of CITF stakeholders as needed.

3.3.2. Leadership Group

The CITF **Leadership Group** membership (see Appendix 1) includes experts from across Canada in matters related to serologic surveillance, immunology, virology, infectious diseases, public health, and clinical medicine. It also includes ex-officio members representing agencies of the Government of Canada, specifically, the Public Health Agency of Canada (PHAC), the Canadian Institutes of Health Research (CIHR), the office of the Chief Scientific Advisor to the Prime Minister, representatives of Provincial-Territorial Ministries of Health,⁴ and McGill University (host of the Secretariat).

The Leadership Group is co-chaired by:

- **Co-Chair, Dr. Catherine Hankins**, *Professor of Public and Population Health, Faculty of Medicine, McGill University*
- **Co-Chair, Dr. David Naylor**, *Professor of Medicine and President Emeritus, University of Toronto*

⁴ There are nine Provincial-Territorial ex-officio members and four expert members of the Task Force who have also taken on Provincial representation roles for Alberta, British Columbia, Manitoba and Quebec for a total of 13 Provincial-Territorial representatives.

A summary of the Terms of Reference (TOR) for the Leadership Group is shown below⁵:

- Establish and oversee the Scientific Strategy of the CITF, which includes:
 - Setting up Working Parties (WPs) in each of the three Scientific Strategy priority areas: Field Studies, Immune Science, and Testing;
 - Working closely with regulatory and standards agencies of Health Canada such as PHAC/NML to accelerate the approval of standards and validation of tests related to serological studies;
 - Setting the key scientific priorities and the timing of their roll-out;
 - Identifying appropriate Implementing Partners (see Section 3.3.7) to lead these studies;
 - Advising calls for proposals and adjudicating the selection process, informed by scientific review and assessment of relevance;
 - Overseeing the responsible implementation of serologic studies including recommending action to overcome bottlenecks, where appropriate;
 - Reviewing, and where appropriate re-directing, priorities as knowledge and context change, as well as identifying supplementary investigations necessary to strengthen the scientific relevance and rigour of the CITF.
- Ensure appropriate collaborative mechanisms are developed to support widespread awareness and engagement of key stakeholders in the work of the CITF;
- Deliberate on and synthesize results of studies in order to communicate them to decision-makers in a timely and clear way; and,
- With the Executive Director, oversee the establishment and activities of a Secretariat charged with coordinating multi-site serosurveys and establishing common platforms that harmonize methods and functions for the efficient operation of serosurveys.

3.3.2.1. Working Parties

Reporting to the Leadership Group, a **Working Party (WP)** is comprised of experts in fields relevant to the three Scientific Strategy Priorities: Field Studies, Immune Science, and Testing. The WP is responsible for monitoring the scientific landscape in its priority area in Canada (and beyond), articulating a strategy and workplan for the LG to review and endorse, and catalyzing the development and implementation of studies. WPs are expected to review, and where appropriate propose to the Leadership Group, a re-direction of priorities as knowledge and context change, identifying supplementary studies necessary to strengthen the scientific relevance and rigour of the CITF. Examples of such studies might include validating dried blood spots for use in antibody testing at

⁵ Full Terms of Reference available from the Secretariat.

home or in remote areas; or modelling infection transmission dynamics using aggregate data emerging from CITF Studies. WPs are led by a member(s) of the Leadership Group (See WP Leader(s), Appendix 1). WP membership includes members of the Leadership Group, as well as the Secretariat, and experts external to the CITF as needed and appropriate.

3.3.3. Executive Committee

The Executive Committee reports to the Leadership Group and comprises the two Co-Chairs, the Executive Director, and six additional rotating members from the Leadership Group. The membership of the Executive Committee is presented in Appendix 2. An important condition for membership is that the individual has no intent to hold or seek funds from the CITF, either as a Principal Investigator or a Co-Investigator on a project that has been funded by the CITF.

A summary of the Terms of Reference for the Executive Committee is shown below⁶:

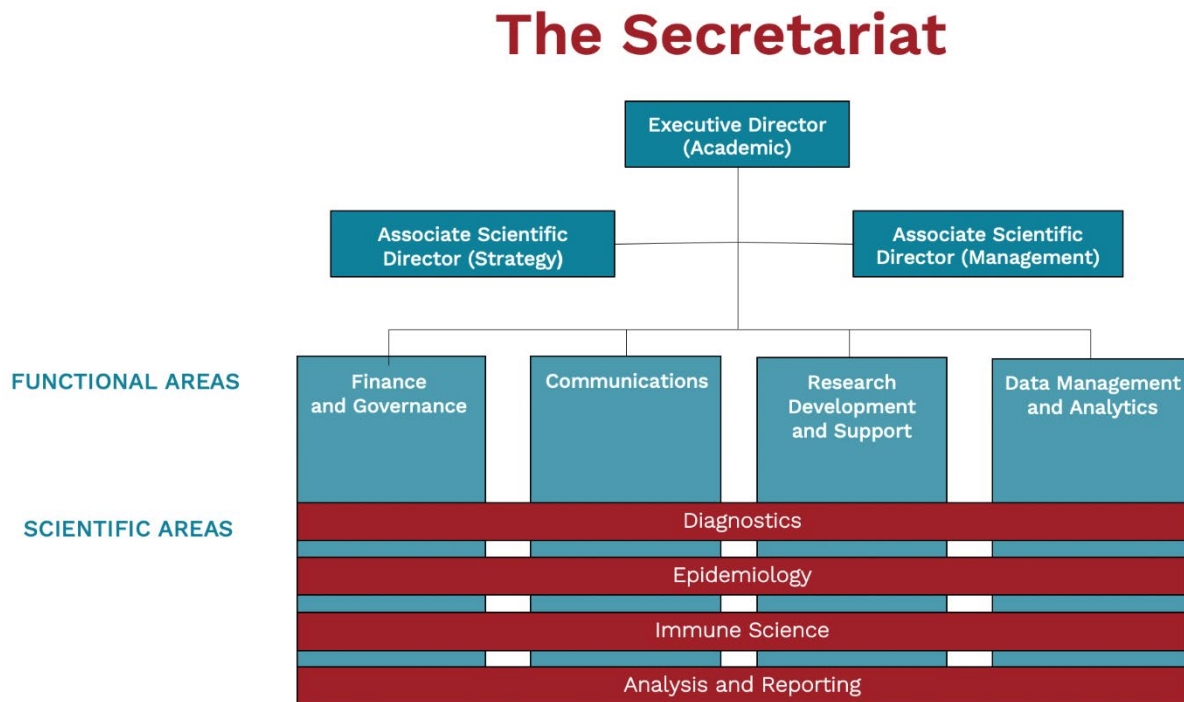
- Set out principles to govern potential Conflicts of Interest (COI) of LG members and procedures to apply them to address COI;
- Ensure that fair and transparent processes for the development, assessment, and implementation of CITF Investment Note Proposals are followed including:
 - Development and application of principles governing sourcing of proposals (sole source, Requests for Expression of Interest (RFEOI), CIHR competitions, other);
 - Development and application of principles in publicly available procedures to guide adjudication of proposals through rigorous and non-conflicted conduct of peer review;
 - Critical review of final budgets attached to proposed investments for value-for-money; and,
 - Setting the terms by which implementation of investments will be phased with a view to ensuring efficient use of resources, e.g. proof of study feasibility, examination of interim results, etc.
- Approve all CITF investments; and,
- Ensure ongoing review of adjudication principles and procedures and adjust as needed.

⁶ The full Terms of Reference are available from the Secretariat.

3.3.4. Secretariat

The Secretariat provides scientific and administrative support that both informs deliberations and implements decisions of the CITF Leadership Group or Executive Committee. These scientific and administrative functions inform the structure and organization of the Secretariat (Figure 3). The roles and responsibilities of the Secretariat are shown in Appendix 3.

Figure 3: Secretariat Structure



The roles and responsibilities of Secretariat members are as follows:

Leadership

The Secretariat Leadership Team comprises the **Executive Director** and **two Associate Scientific Directors**. The **Executive Director** is responsible for implementing the overall mandate of the CITF. Working in close collaboration with the Co-Chairs, the Executive Director ensures effective functioning of the Leadership Group, the Executive Committee, the Working Parties, and the Secretariat. The Executive Director, together with the Co-Chairs, manages representation of the CITF to the Canadian government and other Provincial/Territorial stakeholders and international agencies. The **Associate Scientific Director - Strategy** is responsible for the scientific strategy and workplan of

the CITF, as articulated by the Leadership Group and WPs. The **Associate Scientific Director - Management** is responsible for ensuring effective functioning of CITF governance and finance, communications, research support, and data management.

Scientific Advisors

Scientific Advisors are faculty members from universities across Canada with in-depth expertise in the priorities of the CITF Scientific Strategy. Aligned with the Working Parties, they provide content expertise and oversight to the staff of research associates in the Secretariat and may assist in reviewing proposals and Investment Notes and providing oversight of literature reviews and aggregate data analyses.

Research Development and Support

The Research Support Team provides support to lead investigators and Implementing Partners as they develop Investment Notes for research projects and implement research projects. The team ensures quality and efficiency, and tracks the CITF's attainment of reporting standards, in accordance with Executive Committee and PHAC requirements.

Finance and Governance

The Governance and Finance Team provides support to the Leadership Group with respect to governance, financial monitoring of the Secretariat's budget, and reporting of milestones and deliverables to the Government. The team is responsible for developing terms of reference for key committees, and for supporting Leadership Group meetings and logistics.

Communications

The Communications Team is responsible for developing and implementing the CITF communications strategy, deploying diverse media such as the website, reports, published papers, and interviews with television and print media. The team works closely with the Co-Chairs, Executive Director, and Leadership Group, and in collaboration with the Government of Canada and Implementing Partners, to enhance effective and timely messaging of the work of the CITF.

Data Management and Analytics

The Data Management and Analytics Team establishes the data structures, tools, and data sharing agreements used by the CITF. The team works with the Leadership Group and implementation partners to establish these capacities as well as to structure and steward the CITF data base. Data are managed according to the Data Management Plan.

3.3.5. Secretariat – Supplementary Studies

In the design, implementation, and analysis of CITF studies, it is anticipated that there will be topics related to the Scientific Strategy that Supplementary Studies can address. The topics investigated (study agendas), such as these, are determined by Working Parties and brought forward to the Leadership Group, with a request for the Secretariat to implement them through fair and transparent processes. Implementation decisions by the Secretariat adhere to good research practice and ensure accountability (see Appendix 4).

3.3.6. Host Institution

McGill University is the host institution for the CITF Secretariat, as per a Contribution Agreement signed between the Government of Canada through PHAC and McGill University on May 29, 2020. The timeline of the contribution agreement spans May 17, 2020 to March 31, 2022.

As host, McGill University elected to establish the CITF Secretariat Facilitation and Management Committee (F&MC) to facilitate the work of the CITF Secretariat (see Appendix 5).

3.3.7. Implementing Partners

An Implementing Partner is a Canadian organization – university, health care institution, provincial health authority, private company or incorporated not-for-profit (NFP) Canadian organization – that implements a CITF study as outlined in an Investment Note following approval by the Executive Committee and signing of a Contribution Agreement with PHAC. Responsibilities of approved Implementing Partners include managing study activities, meeting timelines, sharing data with the CITF Secretariat, reporting promptly and accurately, and accounting for agreed use of funding, as defined in the Contribution Agreement and by the CITF Data Management Plan. An Implementing Partner may, on the recommendation of a Working Party and the approval of the Executive Committee, be part of a network of Implementing Partners.

4. Investment Notes

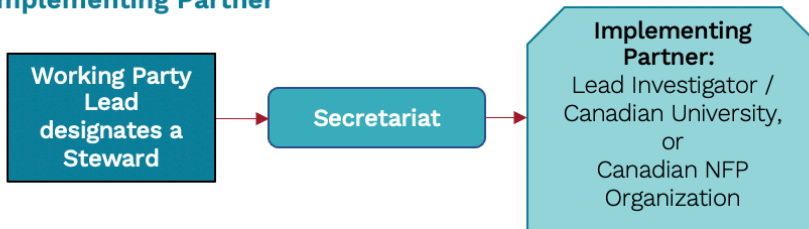
The Investment Note is the primary mechanism through which the objectives of the Scientific Strategy (see Section 2) are translated into specific studies. The CITF developed an explicit process around Investment Note identification, development, review, approval, and financing. The objective is to ensure an appropriate fit with the CITF's mandate, quality in research design, rigorous review, and due process in decision making, including management of conflict of interest. The process of creating an Investment Note involves first identifying a need for a study that aligns with the Scientific Strategy emerging from one of the three Working Parties. The Investment Notes are developed according to a template⁷ that covers critical elements common to all studies and helps to facilitate assessment and review. Proposed studies must be scientifically sound, ethical, feasible, and represent good value-for-money. After review and revision by the Secretariat, the Investment Note is submitted to the Executive Committee (EC) for decision. The EC may decide to provide support to an initial phase of a study with an expectation that support for subsequent phases is contingent on initial results and the need to embrace the rapidly changing nature of the COVID-19 pandemic. Once EC approval is obtained, the Implementing Partner develops a Project Proposal Package with PHAC that leads to a contribution agreement. The process for developing, approving, and funding studies through the Investment Note is shown in Figure 4.

⁷ Investment Note template available from the Secretariat.

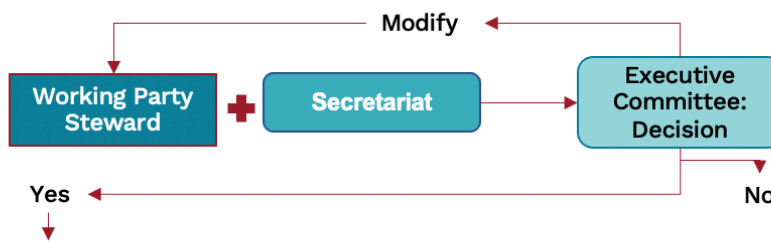
Figure 4: Investment Note Process

Investment Note Process

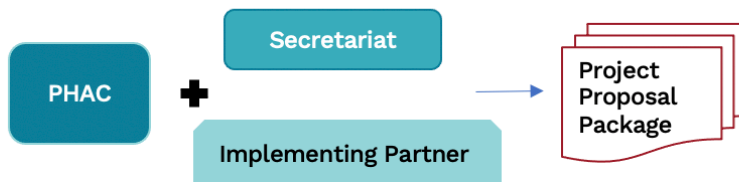
Step 1: Identify the need for a study and identify an Implementing Partner



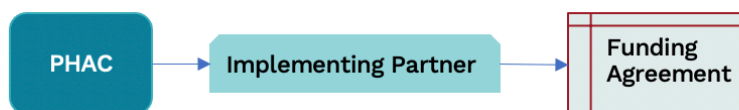
Step 2: Develop, Review and Approve an Investment Note



Step 3: Develop a Project Proposal Package for PHAC



Step 4: Establish and Confirm a Funding Agreement with PHAC



5. Conflict of Interest- Prevention and Management

In the context of the COVID-19 pandemic, the CITF is mandated to implement an agenda of rapid, accurate, and informative studies working with Implementing Partners across Canada with due attention to rigour, ethical standards, and engagement with stakeholders. The CITF recognizes the challenges of balancing a rapid response with due process and is fully committed to manage any potential Conflicts of Interest these circumstances may create.

The COI guidelines⁸ apply to all persons directly engaged with the work of the CITF. All members of the CITF (Leadership Group and Secretariat) who are involved in decision making are required to complete a COI form. Completed forms are posted on the CITF website. During all review processes, Tri-Agency guidelines⁹ are actively used. Details of how COI has been managed during decision-making processes are also posted on the CITF website.

6. Equity, Diversity and Inclusion and Gender-Based Analysis Plus

The Leadership Group of the CITF recognizes the importance of the [CIHR Equity, Diversity, and Inclusion \(EDI\) guidelines](#). The CITF Leadership Group and the Executive Committee ensure that CITF governance, management, and operational members include individuals from diverse backgrounds – with different identities and lived experiences, including individuals from underrepresented communities. The Secretariat and the Implementing Partners also evaluate and incorporate Gender-Based Analysis Plus (GBA+) into the design of Investment Note studies and Supplemental Studies according to guidelines provided by PHAC.

7. Knowledge Translation and Mobilization Strategy

As part of the Investment Note process, the Implementing Partner must include a Knowledge Translation (KT) and Knowledge Mobilization (KM) Plan in the Project Proposal Package. The KT/KM plan must specify the intended audiences and stakeholders and the most appropriate ways to share project results with these audiences and stakeholders (e.g., taking culture, geographic area, gender, language, socio-economic status of audiences into account, etc.).

As a guide, the CITF the CIHR “[Knowledge to Action Process](#)” serves as the model for KT/KM. The CIHR Knowledge to Action Process conceptualizes the relationship between

⁸ The full COI policy is available on our website at the following link:
<https://www.covid19immunitytaskforce.ca/managing-conflict-of-interest/>

⁹ https://www.ic.gc.ca/eic/site/063.nsf/eng/h_90108244.html

knowledge creation and action. The action part of the process can be thought of as a cycle leading to implementation or application of knowledge.

To facilitate knowledge translation, a platform called [SeroTracker](#) has been developed that compiles results from serology surveys supported by the CITF. The SeroTracker Platform, with support from the CITF, is a knowledge hub that tracks and synthesizes findings from SARS-CoV-2 serosurveillance efforts in Canada and worldwide.

Appendices

A1: Leadership Group Membership

Name	Title and affiliation
Catherine Hankins	Co-chair – Professor of Public and Population Health, McGill University
David Naylor	Co-chair – Professor of Medicine and President Emeritus, University of Toronto
Timothy Evans	Executive Director – Professor and Director, School of Population and Global Health, McGill University
Theresa Tam	Ex-officio: Chief Public Health Officer and Head of Public Health Agency of Canada
Mona Nemer	Ex-officio: Chief Science Advisor to Prime Minister, Minister of Science, and Cabinet
Carrie Bourassa	Scientific Director of the CIHR Institute of Indigenous Peoples' Health (IIPH); Professor, Department of Community Health & Epidemiology, College of Medicine, University of Saskatchewan
Vivek Goel	Vice-President, Research and Innovation, and Strategic Initiatives and Professor, Dalla Lana School of Public Health, University of Toronto
Philippe Gros	Ex-officio: Deputy Vice-Principal (Research and Innovation), Professor Department of Biochemistry, McGill University
Scott Halperin	Professor, Pediatrics and Microbiology and Immunology, Dalhousie University, Division of Infectious Diseases; Nominated PI, Canadian Immunization Research Network
Charu Kaushic (WP-Leader)	Scientific Director, CIHR-Institute of Infection and Immunity Professor, Department of Pathology and Molecular Medicine, McMaster University
James D. Kellner (WP-Leader)	Consultant in Pediatric Infectious Diseases and Professor, Departments of Pediatrics, Community Health Sciences, and Microbiology, Immunology & Infectious Diseases, Cumming School of Medicine, University of Calgary and Calgary Zone, Alberta Health Services
Susan Kirkland	Professor and Head University Research Professor, Department of Community Health and Epidemiology, Faculty of Medicine, Dalhousie University / Nova Scotia Health Authority
Gary Kobinger	Professor and Director of the Infectious Diseases Research Centre, Department of Microbiology-infectiology and immunology, Faculty of Medicine, Université Laval

Mel Krajden (WP-Leader)	Medical Director, British Columbia Centre for Disease Control Public Health Laboratory; Professor, Department of Pathology and Laboratory Medicine, University of British Columbia. Provincial representative, British Columbia.
Richard Massé	Special Advisor to the Government of Quebec (public health, epidemiology). Provincial representative, Quebec.
Allison McGeer	Professor of Laboratory Medicine and Pathobiology and Public Health Sciences, University of Toronto
Deborah Money	Professor, Obstetrics & Gynecology, School of Population and Public Health, Faculty of Medicine, University of British Columbia; Clinician Scientist, Women's Health Research Institute
Gina Ogilvie (WP-Leader)	Professor and Canada Research Chair, School of Population and Public Health, University of British Columbia; Senior Public Health Scientist, BC Centre for Disease Control; Associate Director, Women's Health Research Institute.
Jutta Preiksaitis	Professor Emerita of Medicine, Division of Infectious Diseases, University of Alberta
Caroline Quach-Thanh	Professor, Department of Microbiology, Infectious Diseases & Immunology and in the Department of Pediatrics, Université de Montréal; Medical Lead for Infection Prevention & Control, CHU Sainte-Justine
Paul Van Caesele	Medical Director, Cadham Provincial Laboratory, Manitoba Health, Seniors and Active Living; Professor, Departments of Medical Microbiology & Infectious Diseases, and Pediatrics & Child Health, University of Manitoba; Pediatric Infectious Diseases Consultant, Winnipeg Children's Hospital, Shared Health Manitoba. Provincial representative, Manitoba.
Gail Tomblin-Murphy	Vice President of Research, Innovation & Discovery and Chief Nurse Executive of the Nova Scotia Health Authority. Provincial representative, Nova Scotia.
James Talbot	Ex-officio Province/Territory: Alberta, Adjunct Professor of Public Health at the University of Alberta, Former Chief Medical Officer of Health for Alberta and Nunavut. Provincial representative, Alberta.
Heather Hannah	Territorial Epidemiologist and Manager of the Epidemiologist and Surveillance Unit, Northwest Territories. Ex-officio Province/Territory: Northwest Territories
Vanessa Allen	Chief, Microbiology and Laboratory Science, Public Health Ontario Laboratory. Ex-officio Province/Territory: Ontario.
Richard Garceau	Microbiologist - Infectious disease, Microbiology Laboratory Dr. Georges L Dumont University Hospital Centre. Ex-officio Province/Territory: New Brunswick
Marguerite Cameron	Provincial Epidemiologist, PEI Health and Wellness, Chief Public Health Office, Population Health Assessment and Surveillance. Ex-officio Province/Territory: PEI

Michael Patterson	Chief Public Health Officer, Nunavut. Ex-officio Province/Territory: Nunavut
Ed Randell	Professor, Memorial University; Director of Clinical Laboratory Services, Department of Health, Government of Newfoundland Labrador. Ex-officio Province/Territory: Newfoundland and Labrador
Jessica Minion	Laboratory Medicine & Infection Prevention and Control, Regina, Saskatchewan Health Authority. Ex-officio Province/Territory: Saskatchewan
Catherine Elliot	Deputy Chief Medical Officer of Health, Yukon. Ex-officio Province/Territory: Yukon
Stephen Lucas	Ex-officio: Deputy Minister of Health, Canada

A2: Executive Committee Membership

The membership of the Executive Committee includes¹⁰:

- Catherine Hankins, CITF co-chair
- David Naylor, CITF co-chair
- Timothy Evans, Executive Director
- Vivek Goel
- Charu Kaushic
- Mona Nemer, Ex-officio
- Gina Ogilvie
- Jutta Preiksaitis
- James Talbot, Ex-officio Province/Territory

The appointment of Executive Committee Members is by rotation among the LG membership and will be staggered to ensure continuity of deliberations and in full compliance of the Conflict of Interest policy.¹¹

¹⁰ The Full Terms of Reference for the Executive Committee are available from the Secretariat.

¹¹ The CITF's COI policy and its management of COI is available here: <https://www.covid19immunitytaskforce.ca/managing-conflict-of-interest/>

A3: Summary of the Secretariat Roles and Responsibilities

Objective(s)	Activities	Person(s) Responsible / Timelines	Outputs
1. Develop the Task Force Science Strategy	Prepare a draft document of the strategy for discussion and approval by the Leadership Group	Executive Director June 2020	Task Force Science Strategy
2. Establish modus operandi for the implementation of the Science Strategy including, but not limited to, the listed activities	<ul style="list-style-type: none"> Reaching out directly with Health Canada/PHAC to major partners (e.g. Provincial/Territorial ministries/agencies) for collaborative work to answer priority questions of shared interest; Developing calls to the research community for proposals to address priority questions; Conducting fair, rapid, and transparent review of proposals for scientific rigour and relevance; Suggesting top proposals to the Leadership Group for approval; Supporting any Task Force study centres designated by the Leadership Group to implement specific study questions. 	Executive Director; Associate Scientific Directors September 2020	Implementation plan for the Task Force Science Strategy
3. Work closely with PHAC/NML and Health Canada regulatory to understand market supply for SARS-CoV-2 diagnostic tests and serological assays	Develop pooled pro-Canadian procurement mechanisms to negotiate favorable price and timely distribution of antibody tests on behalf of implementing study sites and avoid supply short falls	Executive Director and Associate Scientific Directors On-going	Efficient procurement and distribution of antibody tests to implementing sites
4. Support Implementing Partners and research groups across Canada	Provide supporting guidelines and directives across a core set of common logistical challenges related to: <ul style="list-style-type: none"> Identification of existing biobanks and creation of new biobanks; Laboratory coordination; 	Executive Director; Associate Scientific	Guidelines and directives on specific common elements of studies that are signed off on at the

	<ul style="list-style-type: none"> Laboratory supplies, Common questionnaire elements; Data management – including data structures, models, and transfers 	Directors; Research staff	time of HC/PHAC contracting with implementers
		May-Dec 2020	
5. In consultation with the Leadership Group, facilitate and, in some cases, undertake specific supplementary studies, to develop insights into fundamental issues related to serologic testing and/or SARS-CoV-2 immunity	Undertake smaller scale research investigations directly. These studies are complementary to the major focus areas of the Task Force related to testing, surveys, and immune science	Executive Director; Associate Scientific Directors; Research staff	Research findings presented in the format of scientific papers, presentations, proceedings, etc.
		On-going	
6. Working closely with Health Canada/PHAC to review project proposals for study implementers to ensure requisite alignment and support the efficient and timely distribution of funds	<ul style="list-style-type: none"> Develop a plan for addressing the priority research topics for discussion and decision by the Leadership Group; Establish a mechanism for project selection and rapid allocation of funding; Report on results/findings. 	Associate Scientific Directors	A plan for priority research topics
		On-going	
7. Explore and develop collaborations where appropriate with other countries and international agencies involved in serologic surveys and studies to understand immunity related to SARS-CoV-2	<ul style="list-style-type: none"> Establish links with WHO Solidarity II trial; Participate in international forums and networks to share knowledge and promote collaborations between CITF and international partners 	Executive Director	Participation in WHO Solidarity II. Convening and participating with international partners focused on diagnostics (FIND); and vaccination (CEPI)
		On-going	
8. Provide regular scientific updates on the state of serologic testing, results from other studies, and the	<ul style="list-style-type: none"> Monitor and collect information nationally and internationally; 	Research staff; Associate	Reports, Recommendations,

evolving understanding of immunity related to SARS-CoV-2	<ul style="list-style-type: none"> Prepare regular reports and updates, primarily aimed to serve the scientific community but also in a format that is suitable for the general public (e.g. website). 	<p>Scientific Directors</p> <p>Team</p> <p>On-going</p>	web-based information
9. Foster analysis and synthesis of results to advise decision-makers on implications for response strategies and optimal further deployment of serologic tests	<ul style="list-style-type: none"> Prepare reports and policy briefs on the findings of the Task Force, including their implications, for discussion/approval with the Leadership Group prior to public release; Work with key testing partners including at Health Canada and convene as appropriate to discuss policy issues related to testing. 	<p>Executive Director;</p> <p>Associate Scientific Directors;</p> <p>Research staff;</p> <p>On-going</p>	<p>Task Force Reports and Policy Briefs</p> <p>Convenings with partners to discuss policies on opening up economy and testing strategies.</p>
10. Develop a vital communications capacity for the Task Force	<ul style="list-style-type: none"> Facilitate communication across study investigators and teams, key partners, and the public as appropriate, in Canada's two official languages 	<p>Communication Manager;</p> <p>Associate Scientific Directors</p>	<p>Press releases and conferences</p> <p>Website</p> <p>Articles</p> <p>Other</p>
11. Act as Secretariat to the Leadership Group	<ul style="list-style-type: none"> Provide governance support to the CITF Leadership Group and its Executive Committee (agenda, documents, minutes, and logistics) in the preparation of its meetings 	<p>Manager, Governance & Admin;</p> <p>Associate Scientific Directors</p>	<p>Governance plan and related org charts</p> <p>Terms of reference</p> <p>Meeting documentation</p>
12. Monitor and report on performance measurement and evaluation	<ul style="list-style-type: none"> Determine relevant key performance indicators; Track progress by using available tools and databases such as SciVal. 	<p>Advisor, Key Performance Indicators (KPI);</p> <p>Associate Scientific Directors</p>	<p>Report (on-going)</p> <p>Participate in and convene (where and when appropriate) scientific colloquia related to CITF scientific priorities and results.</p>

A4: Supplemental Studies

Development, Scope and Approval

- 1) A research need identified by one or more Working Party(ies) may be communicated to the Secretariat for implementation using one of the following mechanisms:
 - a) The Secretariat launches a Request for Expression of Interest (RFEOI);
 - b) The Secretariat identifies an Implementing Partner.
- 2) The Secretariat conducts an administrative review of Supplemental Studies for completeness and identifies reviewers for the Proposals (both mechanism 1a and 1b).
- 3) The Secretariat compiles the reviewers' comments and makes a recommendation regarding funding decisions. For each funding level, the decision-maker may approve "as is", ask for modifications, or reject the supplemental funding request.
 - a) Up to \$200,000: The funding decision is made by Working Party Leader(s) (WP- Leader) with the Executive Director (ED) and communicated to the Co-Chairs and the Executive Committee (EC).
 - b) Between \$200,000 and \$500,000: The funding decision is made by the requesting WP- Leader(s), the ED and the two Co-Chairs and communicated to the EC.
 - c) Over \$500,000: The funding decision is made by the requesting WP-Leader, the ED, and the EC.
- 4) If a Supplemental Study is recommended for funding – in full or partial - the CITF Secretariat:
 - a) Contacts the Implementing Partner to discuss results and review next steps.
 - b) Provides the Implementing Partner with a Notice of Award and Acceptance outlining the amount, instalment schedule, and funding conditions.
 - c) 10% of funding for all projects, regardless of the amount, is held back until the final report is accepted by the Secretariat.
- 5) The Implementing Partner accepts the award (Award Acceptance) and provides information on compliance with funding conditions.
- 6) The Secretariat reviews the Award Acceptance and all required documents and confirms completeness.
- 7) The Secretariat releases the funding to the Implementing Partner.
- 8) The Secretariat oversees the funding envelope and is responsible for establishing contractual agreements with the organizations that will undertake the studies.
- 9) Government funding will be transferred to the Secretariat in instalments on a schedule that is adapted to the pace that new studies are approved.
- 10) The Implementing Partner reports to Secretariat as per timeline of reporting milestones in the study through to its conclusion.
- 11) After the final report is received and approved by the Secretariat, the 10% holdback is released.

A5: Host Institution, McGill, Secretariat Facilitation & Management Committee

Mandate

The primary mandate of the CITF Secretariat FM&C¹² is to safeguard that McGill University's obligations towards the Government of Canada, as defined in the Contribution Agreement, are met at all times. This includes financial oversight after receiving and managing the funding provided by Canada under the COVID-19 Serosurveillance and Research program. The mandate also includes facilitating the Secretariat's set up and operations and providing advice and support to the Secretariat leadership (the Executive Director and Associate Scientific Directors) on all aspects of the Secretariat's operations.

¹² The Terms of Reference for the Host Institution and the Secretariat Facilitation & Management Committee are available from the Secretariat.